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ANALYSIS OF AGENDA ITEMS IN PREPARATION FOR THE 56th Session OF THE CODEX COMMITTEE ON FOOD ADDITIVES (CCFA56)

Prepared to Support the Participation of Codex Communities of Practice Supported by GFoRSS

13 – 17 April 2026 • Chongqing, China

Disclaimer and Disclosure of Interest

It is important to note that the proposed analysis and associated conclusions and recommendations stem from the work of independent food regulatory experts. The analysis and associated recommendations or positions are presented as mere suggestions and should not be considered as a direction or final recommendation to the competent authority empowered to develop and endorse Codex positions.

Disclosure of Interest: *Experts involved in the development of this analysis contribute to various food safety and nutrition regulatory capacity building initiatives funded by other Governments, aid agencies, industry and international organizations.*

OBJECTIVES

This document offers an analysis of agenda items to support participation in the 56th Session OF THE CODEX COMMITTEE ON FOOD ADDITIVES (CCFA56), taking place in Chongqing, China, from 13-17 April 2026.

The document is intended for possible use by the Codex communities of practice promoted by the Global Food Regulatory Science Society (GFoRSS), as part of their contribution to enhancing awareness and supporting effective participation in international standard setting meetings (Codex meetings), by representatives from member countries and observers.

This document will offer an analysis of select key agenda item to support the development of positions at the national and regional level. This analysis is indicative in nature and does not represent an official position of the organization, its membership or its management.

The analysis provided in this document offers a factual review of key agenda items of CC, pertaining to:

A. **Agenda Item 3(b):** Proposed draft specifications for the identity and purity of food additives arising from the 100th JECFA meeting
B. **Agenda Item 4(a):** Endorsement and/or revision of maximum levels for food additives and processing aids in Codex standards
C. **Agenda Item 4(a-Add.1):** Endorsement and/or revision of maximum levels for food additives and processing aids in Codex standards (FFCO)
D. **Agenda Item 4(a-Add.2):** Endorsement of the Food Additive Provisions of Commodity Standards
E. **Agenda Item 4(b):** Alignment of the food additive provisions of commodity standards: Report of the Electronic Working Group on Alignment
F. **Agenda Item 5(b):** GSFA: Proposals for new and/or revision of food additive provisions (replies to CL 2025/31-FA)
G. **Agenda Item 8:** Standard for baker's yeast (Step 4)
H. **Agenda Item 10:** Discussion paper on the development of a guideline for the conduct of food safety assessment of cell culture media components used in the food safety assessment of cell culture media components used in the production of cell-based foods

A. Agenda Item 3 (b): Proposed Draft Specifications for the Identity and Purity of Food Additives Arising from the 100th JECFA Meeting (At Step 3)

Document Number: CX/FA 26/56/4

Status in Codex Process: Step 3 (Request for Comments)

Background

- At CCFA55, the FAO/WHO Secretariat presented the outcomes of the 99th JECFA meeting, which included revised specifications for several food additives, flavouring agents, and processing aids.
- The JECFA99 outputs included:
  - Revision of specifications for food additives such as natamycin (INS 235), nisin A, and polyglycerol esters of fatty acids (INS 475).
  - Revision of specifications for ten flavouring agents and development of specifications for three processing aids.
- At JECFA100 (2025), Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated the safety of six (6) food additives and seven (7) processing aids.
  These include:
  - Full specifications for four (4) new food additives (Gardenia Blue, Glycolipids, Thaumatin II);
  - Revised specifications for two (2) existing additives (Ascorbyl palmitate, Gellan gum);
  - Full Specifications for seven (7) enzyme-based processing aids derived from microbial and biotechnological sources, namely:
    i) α-Amylase (JECFA95-1) from *Geobacillus stearothermophilus* expressed in *Bacillus licheniformis*,
    ii) α-Amylase (JECFA95-2) from *Geobacillus stearothermophilus* expressed in *Bacillus licheniformis*,
    iii) α-Amylase (JECFA95-3) from *Rhizomucor pusillus* expressed in *Aspergillus niger*,
    iv) Amyloglucosidase (JECFA95-4) from *Rasamsonia emersonii* expressed in *Aspergillus niger*,
    v) Asparaginase (JECFA95-5) from *Pyrococcus furiosus* expressed in *Bacillus subtilis*,
    vi) β-Amylase (JECFA95-6) from *Bacillus flexus* expressed in *Bacillus licheniformis* and
    vii) Xylanase (JECFA95-9) from *Bacillus licheniformis* expressed in *Bacillus licheniformis*.

These specifications are submitted for consideration at Step 3 of the Codex procedure.

- CCFA56 is requested to review the specifications designated as “Full” for the food additives arising from the 100th JECFA Meeting. with a view to recommending their adoption by CAC49 as Codex Specifications for the identity and purity of food additives, taking into account comments received in response to CL 2026/20-FA.

Overall Purpose

This agenda item aims to review the proposed draft specifications designated as “Full” and assess their scientific robustness and completeness. It also seeks to consider their adoption as Codex specifications while ensuring consistency with JECFA scientific advice within the Codex risk analysis framework.

Key Technical Considerations

- ❖ Specifications should include clear and unambiguous chemical identification, well-defined purity criteria, and appropriate limits for contaminants, including heavy metals.
- ❖ For new food additives, evaluation should be based on JECFA safety assessments, supported by technological justification and consideration of dietary exposure.
- ❖ Revised specifications should reflect updated scientific data and strengthen safety and quality parameters.
- ❖ For processing aids, particularly enzyme preparations, attention should be given to the safety of microbial and biotechnological sources, clear identification of production organisms, and the absence of viable organisms and recombinant DNA where applicable.
- ❖ Special consideration should be given to contaminants in foods intended for infants and young children, with a focus on minimizing exposure to substances such as lead.

Analysis

- The 100th JECFA meeting introduced several substantive revisions to specifications, reflecting important technical and scientific updates.
- For ascorbyl palmitate, JECFA replaced the previous numerical ADI with a group ADI “not specified” (shared with ascorbyl stearate), based on evidence of rapid hydrolysis and negligible systemic exposure.
- JECFA paid particular attention to additives used in infant foods, including ascorbyl palmitate, carob bean gum, and gellan gum. It highlighted that the Codex maximum level for lead in infant formula (0.01 mg/kg) could be exceeded if additives complied with older specifications (e.g. 2 mg/kg lead). To address this, JECFA supported stricter impurity limits and established a lead limit of 0.5 mg/kg for relevant specifications.
- For gellan gum, JECFA clarified the distinction between:
    - general-use gellan gum, and
    - low-acyl clarified gellan gum, specifically intended for infant foods.

  A new dedicated monograph was developed for the latter, with stricter impurity criteria, while the existing monograph was updated and its tentative status removed.
- More broadly, JECFA revised several ADIs, including replacing numerical values with “not specified” ADIs where scientifically justified, reflecting updated risk assessments.
- For processing aids, particularly enzymes, JECFA finalized specifications by incorporating validated analytical methods and standardized unit definitions, addressing previous data gaps.
- As a result, updated data submissions (including batch data and revised activity expressions) allowed the removal of tentative status and the progression of these specifications to full status.

Key discussions and comments

- The document CX/FA 26/56/4 Add.1 compiles comments from nine (9) delegations in response to Circular Letter CL 2026/20-FA.
- Overall, the comments indicate broad support for adoption of the proposed JECFA specifications, recognizing their scientific robustness and international relevance.
- No major scientific objections were raised against individual specifications; the issues identified are primarily implementation related.
- Australia, Egypt, Iraq, Qatar, Chile, and Paraguay explicitly support adoption of all proposed specifications for both food additives and processing aids.
- Ecuador supports the proposals in principle but highlights key challenges for developing countries, including:
    - limited availability and applicability of analytical methods,
    - the need for clearer risk-based justification of purity criteria and impurity limits, and
    - the importance of reasonable transition periods and technical assistance.
- Several delegations emphasized the importance of continuous updating of specifications to reflect evolving manufacturing practices and advances in analytical methods.
- For Gardenia Blue, glycolipids, and Thaumatin II, comments mainly concern technical refinements to the specifications, rather than substantive concerns, indicating that the main challenge lies in implementation capacity rather than scientific acceptability.

Regional Considerations

- Some countries may face challenges related to limited laboratory capacity, restricted access to validated analytical methods, and constraints in routine monitoring. This highlights the need for capacity-building, improved access to standardized methods, and strengthened technical support.
- It is also important that specifications remain clear, practical, and applicable under routine conditions, as overly complex requirements may hinder effective enforcement.

Recommendations

Considering the above analysis for Agenda Item 3b, the following recommendations may guide the regional coordination/ engagement at CCFA56:

- Support the adoption of the proposed draft specifications designated as “Full” arising from the 100th JECFA meeting, recognizing their scientific basis and level of technical maturity.
- highlight the importance of addressing implementation challenges, particularly in developing countries, including access to validated analytical methods, technical cooperation, and appropriate transition periods.
- Emphasize that the specifications should adequately reflect stricter safety requirements for infant foods, ensuring that impurity limits are consistent with Codex standards for finished products.

- Seek clarification on whether the specifications clearly distinguish between general food uses and infant-formula uses, and whether impurity limits are sufficiently explicit to avoid ambiguity in national implementation.

B. Agenda Item 4 (a): Endorsement and/or revision of maximum levels for food additives and processing aids in Codex standards

Document Number: CX/FA 26/56/5

Status in Codex Process: N/A

Background

- In accordance with the section "Relations between commodity committees and general subject committees" in the Codex Alimentarius Commission Procedural Manual, paragraph 61, "All provisions in respect of food additives (including processing aids) contained in Codex commodity standards should be referred to CCFA, preferably before the standards have been advanced to Step 5 of Section 2.1: Procedures for the elaboration of Codex standards and related texts or before they are considered by the commodity committee concerned at Step 7, though such referral should not be allowed to delay the progress of the Standard to the subsequent steps of the procedure.".
- The following food additive and processing aids provisions of Codex standards have been submitted for endorsement since the 55th Session of the Codex Committee on Food Additives (CCFA55) and are listed by:

  i. Technological function, INS number, and food additive name;
  ii. Maximum level;
  iii. ADI (mg additive/kg body weight per day); and
  iv. Notes.

  Table 1 lists the food additive provisions in commodity standards submitted to CCFA56 for endorsement and/or revision of maximum levels. These provisions, forwarded at various steps of the Codex procedure, will be assessed for alignment with the GSFA to ensure consistency before their consideration for adoption by the CAC.

Table 1: Food Additive Provisions in Commodity Standards Submitted to CCFA56 for Endorsement

Committee	Commodity Standard	Region	Codex Status (Step)
FAO/WHO Coordinating Committee for Asia (CCASIA23)	Regional standard for quick-frozen dumplings	Asia	Step 8
FAO/WHO Coordinating Committee for Near East (CCNE12)	Regional standard for doogh (CXS 332R-2018)	Near East	Step 8
	Regional standard for maamoul		Step 8
Codex Committee on Spices and Culinary Herbs (CCSCH8)	Standard for spices derived from dried or dehydrated fruits and berries -Requirements for vanilla	Global	Step 8
	Standard for spices in the form of dried fruits and berries - Requirements for large cardamom		Step 5/8

	Standard for spices in the form of dried seeds - Requirements for coriander		Step 5/8
	Standard for herbs - Requirements for sweet marjoram		Step 5

Analysis

❖ **Regional standard for quick-frozen dumplings (Asia) (for adoption at Step 8) and proposed revisions to the GSFA**

The CCASIA regional standard for quick-frozen dumplings demonstrates a dynamic and evolving alignment with the GSFA. At CCASIA23 (2025), extensive discussions took place regarding the appropriate food category, with agreement to assign FC 06.4.3 (pre-cooked pastas and noodles and like products) as the most suitable reference. However, it was recognized that existing GSFA provisions in this category did not fully reflect actual additive uses in dumplings. Consequently, CCASIA23 agreed to propose specific revisions to the GSFA, including the introduction of new notes to extend the applicability of certain additives to dumplings and adjustments to functional classes (e.g., inclusion of raising agents and firming agents, and broader use of flavour enhancers). This indicates that endorsement of this standard is closely linked to parallel modifications of the GSFA, highlighting an interactive and adaptive approach between commodity standards and the GSFA framework.

Table 2: Proposed revisions for GSFA Table 1 and 2 (REP25/ASIA, Appendix VII, Part B)

Food Category No. ([2])	Food Category Name ([2])	Maximum Use Level ([3])	Comments ([4])
06.4.3	Pre-cooked pastas and noodles and like products		**Add a new note AA:** For use in products conforming to the Regional standard for quick-frozen dumplings (CXS **R-202*) only.

Table 3: Proposed revisions to References to Commodity Standards for GSFA Table 3 Additives

06.4.3	Pre-cooked pastas and noodles and like products
	Acidity regulators, colours, emulsifiers, firming agents, flavour enhancers, humectants, preservatives, raising agents, stabilizers and thickener listed in Table 3 are acceptable for use in foods conforming to this standard.
Codex Standard	Quick-frozen dumplings (CXS **R-202*)

❖ **Regional standard for doogh and for Maamoul (Near East) (for adoption at Step 8) and proposed revisions to the GSFA**

- **The Doogh standard (CXS 332R-2018)** demonstrates a highly structured and product-specific approach to regulation, particularly with respect to food additive use. Additive permissions are differentiated according to product type/plain or flavoured, heat-treated or non-heat-treated, and aligned with multiple GSFA dairy categories as specified in the table below. This reflects a more complex and conditional framework, including technological justification and carry-over co**nsiderat**ions.

Table 4: Permitted Food Additives for Doogh (CXS 332R-2018) by Product Type (REP25/NE Appendix II)

	Doogh (plain, not heat treated)	**Doogh (Flavoured, not heat treated)**	**Doogh (plain, heat treated)**	**Doogh (Flavoured, heat treated)**
Food category of the *General standard for food additives*	01.2.1.1	1.1.4 (Drinks based on fermented milks)	01.2.1.2	1.1.4 (Drinks based on fermented milks)
Acidity regulators:	-	X	X	X
Carbonating agents:	X[b]	X[b]	X[b]	X[b]
Colours:	-	X	-	X
Emulsifiers:	-	X	-	X
Flavour enhancers:	-	X	-	X
Packaging gases:	-	X	X	X
Preservatives:	-	-	-	X
Stabilizers:	X[a]	X	X	X
Sweeteners:	-	X[c]	-	X[c]
Thickeners:	X[a]	X	X	X

[a] Use is restricted to reconstitution and recombination and if permitted by national legislation in the country of sale to the final consumer.

[b] Use of carbonating agents is technologically justified in drinks based on fermented milk only.

[c] The use of sweeteners is limited to milk and milk derivatives-based products energy reduced or with no added sugar.

X The use of additives belonging to the class is technologically justified. In the case of flavoured products the additives are technologically justified in the dairy portion.

– The use of additives belonging to the class is not technologically justified.

- **The Maamoul standard** adopts a harmonized and simplified approach to food additive use. Permitted additives are those specified in Tables 1 and 2 of the General Standard for Food Additives (CXS 192-1995) for food category 07.2.1 (cakes, cookies, and pies, including fruit-filled or custard types), as well as those listed in Table 3 of the GSFA where appropriate.

  The Maamoul provisions do not impose additional conditional restrictions or product-specific limitations, reflecting a fully aligned and flexible framework suitable for bakery products with diverse ingredients.

❖ **Food Additive Provisions in CCSCH Spice and Herb Standards**

The CCSCH standards for **spices and herbs**, including vanilla, large cardamom, coriander, and sweet marjoram, apply a **highly focused and harmonized approach** to the use of food additives. Across all these commodity standards, the only permitted additives are **anticaking agents listed in Table 3 of the General Standard for Food Additives (CXS 192-1995)**. Their use is **restricted exclusively to the ground or powdered forms** of the respective products.

Conclusions and Recommendations

❖ the regional standards reviewed, including Doogh, Maamoul, and selected spices and herbs, reflect a balanced approach to food additive use, taking into account product-specific characteristics, technological justification, and practical considerations. The Doogh standard applies a differentiated and conditional framework appropriate for complex dairy products, while

Maamoul and the spice and herb standards adopt simplified, harmonized provisions directly aligned with GSFA, ensuring clarity and ease of implementation.

❖ The following recommendations may guide the regional coordination/ engagement at CCFA56:

- Support the existing additive provisions in the Regional Standards for Doogh, Maamoul, and the CCSCH spices and herbs, noting their alignment with GSFA and their technical justification.
- Support the continuation of differentiated additive frameworks where justified by product characteristics, as in Doogh, while maintaining simplified, harmonized approaches for products with less complexity, such as Maamoul and spices.
- Emphasize clear cross-references to GSFA tables and procedural manuals in all regional standards to ensure clarity, facilitate compliance, and support uniform enforcement across member countries.
- Encourage CCFA56 to consider aligning additive provisions across similar traditional products to promote consistency and avoid trade barriers, while respecting product-specific technological needs.

C. Agenda Item 4(a-Add.1): Endorsement and/or revision of maximum levels for food additives and processing aids in Codex standards (FFCO)

Document Number: CX/FA 26/56/5 Add.1

Status in Codex Process: N/A

Background

- At CCFO29 (2026), the Committee agreed to forward the proposed draft standard for microbial omega-3 oils to CAC49 for adoption at Step 5 and simultaneously forwarded the related food additive provisions to CCFA for endorsement. In addition, CCFO29 requested CCFA to advise on the appropriate GSFA food category, as the current GSFA system does not explicitly include oils derived from microbial sources.

❖ **Part A: Determination of Appropriate Food Category**

CCFO29 requested CCFA to advise on the appropriate categorisation of microbial omega-3 oils in the General standard for food additives (GSFA, CXS 192-1995), noting the following:

- No existing food category (FC) adequately covers microbial omega-3 oils. Neither **FC 02.0 (Fats, oils and emulsions)** nor its subcategories explicitly include oils of microbial origin.
- CCFO29 recommended establishing a new subcategory under **FC 02.1 (Fats and oils essentially free from water)** within the parent category FC 02.0, described as:

> **02.1.4 Microbial oils and fats:** Edible fats and oils obtained from oleaginous microorganisms, including but not limited to microalgae, protists, fungi, or yeast, and not derived from plants or animals. These oils and fats are intended for use as edible fats and oils or as ingredients in foods. This category also encompasses concentrated forms of specific fatty acids.

- CCFO29 also recommended updating **FC 02.0 and FC 02.1** to include microbial oils:
  - **02.0 Fats and oils, and fat emulsions**: Includes all fat-based products derived from vegetable, animal, microbial, or marine sources, or their mixtures.
  - **02.1 Fats and oils essentially free from water**: Edible fats and oils composed mainly of triglycerides of fatty acids from vegetable, animal, microbial, or marine sources.

❖ **Part B: Endorsement of Food Additive Provisions**

- CCFO29 agreed to forward the relevant food additive provisions for microbial omega-3 oils to CCFA for endorsement, ensuring that the additive framework is technologically justified and aligned with GSFA tables.
- The proposed draft standard allows the use of antioxidants, sequestrants and emulsifiers in accordance with Tables 1 and 2 of the General Standard for Food Additives **(GSFA, CXS 192-1995),** under a food category to be determined.
- Flavourings used in products covered by this standard should comply with the Guidelines for the Use of Flavourings **(CXG 66-2008).**
- Annex to the Proposed Draft Standard for Microbial Omega-3 Oils **(CX/FA 26/56/5 Add.1**), containing the list of acceptable food additives and their associated maximum levels.

CCFA56 is invited to:

i. Advise on the appropriate GSFA categorisation for microbial omega-3 oils within the GSFA, including consideration of the proposed new category and related amendments to the GSFA food category system (as outlined in Part A).

ii. Endorse the proposed food additive provisions in the draft standard, as presented in Part B and its Annex, taking into account their consistency with the GSFA.

Overall Direction of the Proposal

❖ The document focuses on two main elements, namely the determination of an appropriate food category within the GSFA and the endorsement of the related food additive provisions in the proposed draft standard.

The proposal reflects a clear Codex direction toward:

- Accommodating innovative and novel food products such as microbial oils.
- Updating the GSFA framework to ensure inclusivity of all relevant sources (plant, animal, marine, and microbial).
- Maintaining consistency by integrating new products within the existing GSFA structure, rather than creating parallel systems.

Key Issue

❖ The key issue is the absence of a suitable GSFA food category for microbial oils. The current categories under FC 02.0 and FC 02.1 do not explicitly include oils derived from microbial sources, creating a classification gap.

❖ To address this, CCFO29 proposed:

i. The establishment of a new subcategory, **FC 02.1.4 Microbial oils and fats**, under FC 02.1 **Fats and oils essentially free from water** and

ii. Revising the descriptions of FC 02.0 and FC 02.1 to explicitly include microbial sources.

- **FC 02.0** to include vegetable, animal, microbial or marine sources; and
- **FC 02.1** to reflect the broader range of edible oils for human consumption.

Analysis

- The need for a new GSFA category is technically justified because microbial omega 3 oils are not limited to conventional triglyceride oils and may include phospholipids, glycolipids, fatty acid ethyl esters and re esterified triglycerides. This indicates that the current wording of FC 02.1, which mainly refers to triglycerides, may not fully capture the diversity of these products.

- The proposed categorisation approach is structurally sound and aligned with the GSFA hierarchy. It preserves the integrity of the classification system, avoids inconsistent or ad hoc categorisation and represents a policy level improvement that supports the future inclusion of similar novel products.

- Regarding food additives, the proposal follows a consistent and harmonised approach by relying on GSFA Tables 1 and 2 without introducing independent maximum levels. The inclusion of a defined list of additives and their maximum levels in the Annex further strengthens transparency and clarity.

- The restriction of additives to antioxidants, emulsifiers and sequestrants is technologically justified. Microbial omega 3 oils are rich in highly unsaturated fatty acids and are therefore particularly susceptible to oxidation.

    - Antioxidants are used to prevent or delay oxidation,
    - Emulsifiers improve stability and product appearance, reduce crystallization and cloudiness at low temperatures,
    - Sequestrants bind trace metals that can accelerate oxidation.

- From a safety perspective, all proposed additives are supported by JECFA evaluations, either through established acceptable daily intakes or GMP or not specified designations. This demonstrates alignment with internationally recognised safety standards and does not raise immediate safety concerns.

- The approach to maximum levels is balanced, combining GMP provisions for low risk additives with numerical limits for more potent substances such as certain antioxidants. This ensures both flexibility in use and appropriate control of higher risk additives.

Other considerations

This item also has links with other Codex committees. CCFO29 requested:

- CCCF to consider extending MLs for arsenic and lead to microbial omega-3 oils,
- CCFL to endorse labelling provisions,
- CCMAS to endorse methods of analysis.

Conclusion and recommendations

- Agenda Item 4(a-Add1) is primarily about updating the GSFA so that it can properly accommodate microbial oils as a new class of edible oils.
- The proposed additive provisions are technically justified, but their endorsement depends on having a suitable and coherent GSFA category.
- Considering the above analysis for Agenda Item 4(a-add.1), the following recommendations may guide the regional coordination/ engagement at CCFA56:

1. Agree to establish a new food category (FC 02.1.4) for microbial oils and fats within GSFA.
2. Support the expansion of FC 02.0 and FC 02.1 definitions to explicitly include microbial oils sources, ensuring clarity and consistency.
3. Agree to endorse the proposed food additive provisions limited to antioxidants, emulsifiers and sequestrants, as they are aligned with GSFA Tables 1 and 2.
4. Ensure consistency between the assigned food category and additive permissions to avoid regulatory gaps.
5. Encourage careful monitoring of antioxidant levels, given the high susceptibility of omega-3 oils to oxidation.
6. Recommend future review, particularly as additional microbial-derived products emerge in the market.

D. Agenda Item 4(a-Add.2): Endorsement of the Food Additive Provisions of Commodity Standards

Document Number: CX/FA 26/56/5 Add.2

Status in Codex Process: N/A

Background

- ❖ At CCFA55(2025), the Physical Working Group (PWG) on Endorsement and Alignment introduced a new approach by preparing recommendations simultaneously on the food additive provisions of certain commodity standards and on the corresponding amendments to the General Standard for Food Additives (GSFA, CXS 192-1995).
- ❖ However, this approach also limits the time available for CCFA to adequately review proposed GSFA amendments, as these may be presented for the first time during the Physical Working Group discussions. In recognition of these challenges, an addendum to the working documents (CX/FA 26/56/5 and CX/FA 26/56/5 Add.1) has been prepared to provide advance information on proposed GSFA amendments where feasible. In some cases, the Chair considered it premature to propose such amendments at this stage, and these are highlighted for further discussion.

List of Annexes

Annex 1: Explanatory document – questions, comments and chair's proposals for the PWG

Annex 2: Proposed amendments to the food additive provisions of the Regional standard for quick-frozen dumplings (Asia) (submitted by CCASIA) and to Tables 1, 2 and 3 of the GSFA relating to the alignment of that standard

Annex 3: Proposed amendments to the food additive provisions of the Regional standard for maamoul (Near East) (submitted by CCNE), and to Tables 1, 2 and 3 of the GSFA relating only to the alignment of that standard.

Analysis

The CX/FA 26/56/5 Add.2 document addresses the endorsement of food additive provisions in commodity standards and their **alignment with the General Standard for Food Additives (GSFA, CXS 192-1995)**.

A key development highlighted is the **concurrent approach** to:

- Endorsing food additive provisions in commodity standards
- Introducing corresponding amendments to the GSFA

- While this approach improves efficiency and consistency, it also introduces challenges related to **limited review time** for CCFA.
- The explanatory document in ANNEX 1 addresses issues arising from **the endorsement of food additives in new or revised commodity standards** and the consequential amendments required in the GSFA. It presents the Chair's proposals and draft GSFA amendments for consideration by the Physical Working Group (PWG). The focus is on ensuring **alignment between commodity standards and the GSFA** while maintaining consistency, transparency, and scientific justification.

1) Regional Standard for Asia: Quick-Frozen Dumplings

- Quick-frozen dumplings are aligned with GSFA category FC 06.4.3 (pre-cooked pasta, noodles, and similar products).
- Functional classes justified include acidity regulators, colours, preservatives, stabilizers, humectants, thickeners, flavour enhancers, and emulsifiers (Tables 1 & 2), with additional classes in Table 3.
- **Chair's proposals:**
  - Permit additives in Tables 1 & 2 and Table 3 according to their functional classes.
  - Introduce a new note to allow specific "exclusive" additives (e.g., carmines INS 120, beta-carotenes INS 160a, phosphates, propylene glycol alginate INS 405, sucrose esters INS 473/474, sulfites INS 220–225/539) to be used in quick-frozen dumplings.
  - Revise Note 194 to clarify exclusive use in instant noodles and prevent conflict with the new note.

2) Regional Standards for the Near East

- ***Doogh***
  - Additive work has been on hold pending alignment with the fermented milk standard (CXS 243-2003).
  - Further technical justification is required, and endorsement is proposed to be held until CCNE completes its review.
- ***Maamoul***
  - Additives in Tables 1 & 2 of GSFA for FC 07.2.1 (cakes, cookies, pies) or listed in Table 3 are acceptable.
  - The Chair proposes permitting all additives from Tables 1 & 2 and referencing Table 3 without changes, ensuring full alignment with GSFA provisions.

3) Standards for Culinary Herbs and Spices

- Four standards were presented for endorsement related to anticaking agents in Table 3.
- Current issues include herbs being in the Annex to Table 3 and questions about including spices in Table 3, pending CCSCH guidance.
- **The Chair proposes** delaying endorsement until CCSCH clarifies Table 3 usage. References should identify specific anticaking agents and link to Tables 1 & 2 where appropriate.

4) Fats and Oils – Microbial Omega-3 Oils

- CCFO29 forwarded the draft standard for microbial omega-3 oils for adoption, including additive provisions.
- A new category, FC 02.1.4 – microbial oils and fats, is proposed to cover products not in current GSFA categories.
- Additives endorsed include antioxidants, emulsifiers, and sequestrants (Tables 1 & 2), with no Table 3 provisions required.
- **The Chair proposes** referring the creation of FC 02.1.4 to the GSFA EWG and endorsing additive provisions for incorporation into the GSFA while awaiting formal category endorsement.

Conclusion and Recommendations

- ❖ Agenda Item 4(a-Add2) focuses on procedural and structural alignment rather than new technical evaluations. Microbial oils and Maamoul are ready for endorsement and GSFA integration. Doogh and spice standards require further technical review before endorsement. This approach balances progress with GSFA consistency.
- ❖ Considering the above analysis for Agenda Item 4a Add.2, the following recommendations may guide the regional coordination/ engagement at CCFA56:

1. Support the concurrent approach for endorsement and GSFA alignment, while ensuring sufficient review time.
2. Agree to endorse additive provisions for standards that are fully aligned with GSFA (e.g., dumplings, Maamoul), with necessary notes.
3. Agree to hold endorsement where scientific justification is incomplete (e.g., Doogh).
4. Support the use of GSFA-based approaches rather than creating standalone additive lists.
5. Encourage simplification of GSFA notes system, to avoid excessive complexity.
6. Request further clarification on the use of Table 3 for herbs and spices before endorsement.
7. Support continued work through EWG for unresolved structural issues (e.g., microbial oils category).

E. Agenda Item 4(b): Alignment of the food additive provisions of commodity standards: Report of the Electronic Working Group on Alignment

Document Number: CX/FA 26/56/6

Status in Codex Process: N/A

Background

- ❖ The work of CCAFRICA on the development of a **Regional Standard for Dried Meat** was initiated at CCAFRICA21 (2014), with the first indication that the standard would include food additive provisions at CAC39
- ❖ At CCFA55, an Electronic Working Group (EWG) chaired by Canada was established to:

a. align the CCAFRICA regional standards: Regional standard for fermented cooked cassava-based products (Africa) (CXS 334R-2020), Regional standard for fresh leaves of Gnetum spp. (Africa) (CXS 335R-2020), Regional standard for dried meat (Africa) (CXS 350R-2022);

b. align the CCLAC regional standards: Regional standard for Culantro coyote (Latin America and the Caribbean) (CXS 304R-2011), Regional standard for lucuma (Latin America and the Caribbean) (CXS 305R-2011);

c. align the CCNASWP regional standards: Regional standard for kava products for use as a beverage when mixed with water (North America and South West Pacific) (CXS 336R-2020), Regional standard for fermented noni fruit juice (North America and South West Pacific) (CXS 356R-2023);

d. align the CCCPC commodity standard: Standard for cocoa butter (CXS 86-1981);

e. align the CCFFP commodity standard: Standard for quick frozen raw squid (CXS 191-1996), Standard for live and raw bivalve molluscs (CXS 292-1995), Standard for live abalone and for raw fresh chilled or frozen abalone for direct consumption or for further processing (CXS 312-2013);

f. align the CCPFV commodity standard: General standard for fruit juices and nectars (CXS 247-2005);

g. in collaboration with the Codex Secretariat and based on the functionality of the new GSFA database, to develop a stepwise approach for Table 3 Notes, including:

   i. Deleting provisions for Table 3 additives in FCs not listed in the annex to Table 3 but included in Tables 1 and 2; and

   ii. Revising the fifth column of Table 3 Notes.

Analysis

- The EWG proposed to align food additive provisions in commodity standards with the GSFA by updating references to Tables 1, 2, and relevant food categories. This includes replacing outdated provisions with harmonized GSFA-based approaches.
- The EWG proposed improvements to Table 3, including better structure, clearer notes, and removal of redundant provisions. In addition, the use of certain GSFA notes (e.g. “as consumed”) should be reviewed to ensure consistent application.
- The work covers several Codex committees and multiple commodity standards (e.g. CCAFRICA, CCNASWP, CCCPC, CCFFP).
- Only one consultation round was conducted.
- The EWG reached consensus on the overall approach to aligning commodity standards with the GSFA, including the use of GSFA as the main reference framework, harmonized wording based on the Codex Procedural Manual, and many straightforward technical amendments. There was also general agreement on the need to improve the structure and clarity of Table 3 notes.
- Several conceptual questions remain unresolved, particularly regarding the correct interpretation of the GSFA food category system. These include misunderstandings of the hierarchy (parent vs subcategories), difficulties in assigning appropriate categories to complex or multi- characteristics products (e.g. fermented, processed, frozen), which may not fit neatly into a single category and debates on how certain products (e.g. raw materials like cocoa butter) should be classified within the GSFA structure.

- ❖ On the technical side, issues persist in the correct referencing of food categories, especially the need to use specific subcategories instead of parent categories. Additional challenges include handling products that fall under multiple categories, correcting inconsistencies in previously aligned standards, and improving the practical application and formatting of Table 3 provisions.
- ❖ Some alignment issues fall outside the direct mandate of CCFA, particularly where clarification of the product definition or scope is required. In such cases, input from the relevant commodity committees, including regional committees such as CCAFRICA and CCNASWP, is essential to ensure that the assigned GSFA food categories accurately reflect the nature of the products covered by the standards.
- ❖ Proposed amendments to specific commodity standards
  - **Cassava products (CCAFRICA):** The classification requires further review, particularly regarding whether products should be assigned to cooked or fermented vegetable categories.
  - **Dried meat (CCAFRICA):** It is proposed to replace the general food category (08.2) with more specific subcategories to better reflect the nature of the products and ensure correct application of GSFA provisions.
  - **Kava products (CCNASWP):** Consideration should be given to including multiple relevant food categories to reflect the different product forms (e.g. fresh, dried, or frozen).
  - **Cocoa butter (CCCPC):** The current classification should be reviewed, with consideration of alternative placement, such as under fats and oils or within a dedicated subcategory.
  - **Fish (CCFFP):** A review is needed to identify and correct inconsistencies arising from previous alignment work.

Key Amendments in Annexes

Annex 1: Explanatory Document

- Presents comments, questions, and proposals from the Chair to guide EWG discussions.
- Identifies key technical and conceptual issues requiring further consideration, including by the Physical Working Group (PWG).

Annex 2: Amendments to CCAFRICA Regional Standards

Updates to food additive provisions in selected regional standards, including:

- **Cassava-based products** (classification under review: cooked vs fermented categories.
- **Dried meat products** (replacement of general category 08.2 with specific subcategories)

Annex 3: Amendments to CCNASWP Regional Standards

Proposed revisions to food additive provisions for **Kava products** (consideration of multiple GSFA food categories reflecting different product forms such as fresh, dried, or frozen)

Annex 4: Amendments to CCCPC Commodity Standards

Proposed amendments to food additive provisions for **Cocoa butter** (review of current

classification and consideration of alternative placement, e.g. fats and oils or a dedicated subcategory).

Annex 5: Amendments to CCFFP Commodity Standards

Proposed revisions to previously aligned fish and seafood standards:

- Identification and correction of inconsistencies and technical errors
- Development of a structured approach for systematic review

Annex 6: Food Category Alignment Issues (Cross-cutting)

- Revision of GSFA food category references to ensure use of appropriate subcategories instead of parent categories
- Consideration of multiple category assignments for products with diverse characteristics

Annex 7: Table 3 Notes Development

- Ongoing work to improve the structure, clarity, and consistency of Table 3 notes
- Review of applicability and removal of redundant or unclear provisions
- Consideration of issues related to GSFA notes (e.g. “as consumed”)

Key Updates to Food Additive Provisions and GSFA Alignment

1) Food Category Alignment

- Replacement of broad categories with more specific GSFA subcategories
- Improved consistency in the application of GSFA hierarchy

2) Clarification of Product Classification

- Review of classification for products with multiple characteristics (e.g. cassava, kava)
- Reassessment of classification for certain raw materials (e.g. cocoa butter)

3) Correction of Legacy Issues

- Identification of inconsistencies in previously aligned standards (e.g. fish and seafood)
- Proposal for systematic correction process

4) Harmonization of Drafting

- Standardization of wording in line with Codex Procedural Manual
- Clear references to GSFA Tables 1, 2, and 3

5) Table 3 Improvements

- Enhanced structure and usability of notes
- Alignment with GSFA database and practical application

Key issues and questions requiring consideration by the PWG

1) Issues related to CCAFRICA regional standards

- A key discussion point relates to the alignment of the standard for **fermented cooked cassava-based products**, where uncertainty remains regarding the most appropriate GSFA food category. While the product is currently linked to a category covering cooked vegetables, several members highlighted that its fermented nature may justify classification under the fermented vegetables category. This presents a challenge on how to classify products with multiple processing characteristics within the GSFA framework. It was therefore agreed that further clarification from CCAFRICA is necessary to confirm the appropriate categorization, as the committee is responsible for defining the product scope. Pending this input, alignment cannot be finalized.

- Discussions on the regional standard for **dried meat** revealed a technical inconsistency in the use of GSFA food categories, particularly the reference to a parent category (08.2) instead of more specific subcategories. Members noted that this approach may unintentionally exclude certain permitted additives due to the hierarchical structure of GSFA. There was general agreement for considering more specific subcategories (e.g. those covering dried or heat-treated meat products), but it was also acknowledged that clarification is needed from CCAFRICA regarding the exact scope of products covered, including whether comminuted meats are included. This reflects both a technical and conceptual issue in aligning standards with GSFA.

2) Issues related to CCNASWP regional standards

- The alignment of the standard for **kava products** also raised questions regarding the appropriate GSFA food categories. While the standard is currently linked to certain fresh and processed vegetable categories, the description of the product includes forms such as peeled, fresh, dried, and frozen rhizomes, suggesting that additional categories may be relevant. This highlights the challenge of aligning products that exist in multiple physical forms within a single framework. Members agreed that further input from CCNASWP is required to confirm whether additional food categories should be referenced before finalizing alignment.

3) Issues related to CCCPC standards

- Another important discussion concerned the classification of **cocoa butter,** where several members questioned its current placement under a GSFA category intended for cocoa-based spreads and fillings. It was noted that cocoa butter is a raw material used in chocolate manufacturing, rather than a finished product, raising doubts about the appropriateness of its current classification. Different views were expressed, including placing it under fats and oils or creating a new subcategory under cocoa products. While there was general agreement that the current classification is problematic, no consensus was reached on an alternative. It was therefore proposed to defer alignment and consult CCFO, given its mandate over fats and oils, before proceeding further.

- In the case of **fish and seafood standards**, the EWG identified that several standards had already been aligned in previous sessions but contain errors and inconsistencies affecting clarity and coherence. Rather than proceeding with further amendments, it was agreed that a more systematic review is needed. The Chair indicated the intention to consult CCFFP and develop a structured

action plan to address these issues. This highlights the need to revisit past alignment work to ensure consistency across standards.

Conclusion and Recommendations

- While the EWG achieved general agreement on the overall approach to alignment and on many proposed amendments, several issues remain outstanding. These relate in particular to the interpretation of the GSFA food category hierarchy, the classification of complex or multi-dimensional products, inconsistencies in previously aligned standards, and the need for further clarification regarding the application of Table 3 notes.
- These challenges highlight that alignment is not only a technical exercise but also requires conceptual clarity and effective coordination across Codex committees. Addressing these issues will require further technical work, as well as input from relevant commodity committees, before full and consistent alignment can be achieved.
- Considering the above analysis, the following recommendations may guide the regional coordination/ engagement at CCFA56:
  1. Support endorsement of alignment proposals where there is general agreement and no outstanding technical issues.
  2. Provide a clear and substantiated regional position to CCFA on the classification of mixed zaatar under either food category 12.2.1 or 12.2.2, as specifically requested by CCFA55 (2025).
  3. Support finalization of unresolved matters, with a focus on refining additive categorization and resolving alignment inconsistencies.

F. Agenda Item 5(b): GSFA - Proposals for New and/or Revision of Food Additive Provisions

Document Number: CX/FA 26/56/8

Status in Codex Process: N/A

Background

Under Agenda Item 5b, several Members and Observer organizations submitted proposals for the inclusion of new food additives or the revision of existing provisions in the General Standard for Food Additives (GSFA).

Overview of Submissions

- The proposals submitted by:
  - Japan
  - Republic of Korea
  - EU Specialty Food Ingredients
  - International organizations (IFAC, IACM, ISDI, EU SPI)
- These proposals include:
  - Introduction of new additives (e.g., Gardenia Blue).
  - Revision of existing provisions (e.g., Steviol glycosides).
  - Extension of use conditions for approved additives (e.g., Rosemary Extract).
- Each proposal is supported by:
  - Technological justification.
  - Safety evaluation (mainly by JECFA).
  - Proposed maximum use levels.

Analysis

- The document CX/FA 26/56/8 presents proposals from Members and observer organizations to introduce new food additives or revise existing provisions in the GSFA (Tables 1, 2, and, where applicable, Table 3). These proposals follow Circular Letter CL 2025/31-FA and are primarily based on recent evaluations by JECFA, including the outcomes of its 100th meeting (2025), with assigned ADIs either numerical or "not specified."
- The submissions demonstrate a strong scientific foundation and cover a broad spectrum of additives, including colours (e.g., Gardenia Blue, annatto extracts), sweeteners (e.g., steviol glycosides), antioxidants (e.g., rosemary extract, ascorbyl esters), preservatives (e.g., nisin, dimethyl dicarbonate), and stabilizers/thickeners (e.g., carob bean gum).
- Several proposals reflect emerging trends in the food sector, such as the use of "natural" additives (e.g., rosemary extract, Gardenia Blue) and reduced-sugar formulations (e.g., steviol glycosides), highlighting both market demand and technological innovation. At the same time, submissions involving sensitive categories, such as infant formula (ascorbyl palmitate), require particular caution, even when supported by a "not specified" ADI—due to the vulnerability of the target population.
- Some proposals explicitly request modifications to existing standards (e.g., fermented milks, jams), while others may have indirect implications for related standards.
- A consistent pattern emerges across the proposals: each additive is justified by a clear technological function, such as enhancing appearance (colours), improving taste (sweeteners), preventing oxidation (antioxidants), ensuring microbiological safety (preservatives), or maintaining texture and stability (thickeners).

1) Gardenia Blue (INS 165) – Submitted by Japan

- The proposal seeks to introduce Gardenia Blue as a colour additive across a wide range of food categories, including dairy products, confectionery, beverages, and snack foods. From a technological perspective, the additive fulfills a clear function as a colouring agent, contributing to improved visual appearance and product consistency, while also responding to market demand for alternative blue colourants.
- From a safety standpoint, the additive has been evaluated by JECFA, which established an ADI of 0–7 mg/kg bw/day. The proposed uses are accompanied by exposure assessments indicating that anticipated intake levels remain below the ADI, with application limited to the minimum levels necessary under Good Manufacturing Practice (GMP).
- However, the breadth of the proposed food categories raises some considerations. The cumulative exposure resulting from multiple uses across diverse food groups may require further verification. In addition, certain proposed applications extend beyond those explicitly covered in the original JECFA exposure scenarios, suggesting that additional refinement of exposure assessments may be warranted to ensure continued safety.

2) Steviol Glycosides (INS 960 series) – Submitted by the Republic of Korea

- This proposal aims to revise existing GSFA provisions for steviol glycosides in food supplements, notably by removing the restriction limiting their use to chewable supplements.

The primary technological justification is to improve organoleptic properties, particularly by masking the inherent bitterness of active ingredients commonly present in supplements.

- JECFA has established an ADI of 0–4 mg/kg bw/day (expressed as steviol), and steviol glycosides are already widely recognized and used as high-intensity sweeteners in various food categories. The proposed revision reflects current manufacturing practices and aligns with broader applications across different supplement formats.
- From a regulatory perspective, the expansion of use is not expected to significantly impact overall exposure, which is anticipated to remain within established safety margins. Nonetheless, maintaining clear labelling provisions is essential to ensure transparency and allow consumers to make informed choices.

3) Rosemary Extract (INS 392) – Submitted by EU Specialty Food Ingredients

- The proposal introduces or extends the use of rosemary extract as an antioxidant in multiple food categories, particularly fats, oils, dairy powders, and spreads. Technologically, the additive serves to delay oxidation, thereby improving shelf life and preserving product quality. Its efficacy is linked to its active components, carnosic acid and carnosol, with use levels expressed accordingly.
- JECFA has recently re-evaluated rosemary extract and established an ADI of 0–0.6 mg/kg bw/day (expressed as carnosic acid and carnosol), concluding that current exposure estimates do not raise safety concerns. The additive is already permitted in several Codex food categories, and the proposal demonstrates compatibility with existing standards, particularly those related to fats and oils.
- However, careful attention is required to ensure consistency with existing Codex commodity standards, especially in cases where antioxidants are not permitted (e.g. certain virgin oils or specific standardized products). Maintaining these exclusions and ensuring harmonized application across categories will be important to avoid regulatory inconsistencies.

4) Annatto Extracts (INS 160b, bixin- and norbixin-based) – Submitted by the International Association of Color Manufacturers

- The proposal aims to revise the existing provisions for annatto extracts, both bixin- and norbixin-based, as a food color in multiple snack categories, particularly potato-, cereal-, flour-, or starch-based products. Technologically, the additive serves to provide the desired yellow to orange color in flavoured snacks, ensuring consistency and consumer appeal.
- The proposal includes revisions to Notes 603 and 185 to clarify maximum use levels (up to 100 mg/kg for flavoured snacks such as barbecue, cheese, hot/spicy, tortillas, nachos, and chips), reducing confusion in international trade and aligning regulatory text with practical application. Unflavoured crackers and snacks are excluded, as they fall under different food categories.
- JECFA evaluated annatto extracts in 2006, establishing an ADI of 0–12 mg/kg bw for bixin and 0–0.6 mg/kg bw for norbixin. Refined dietary intake assessments indicated that estimated exposure from all foods remains very low, up to 0.2% of the ADI for bixin and up to 4% of the ADI for norbixin, demonstrating that current and proposed uses are well within safe levels. The technological need is justified, as color is a functional requirement for consumer recognition and product identity in flavoured snack products.

- ❖ While the proposal is not linked to any corresponding commodity standard, it ensures harmonized application within the GSFA and helps avoid inconsistencies in international trade. The proposed use is not expected to mislead consumers, as the additive's function as a colorant will be clearly declared on product labels.

5) Nisin A (INS 234) – Submitted by International Food Additives Council (IFAC)

- ❖ The proposal seeks to revise existing provisions for nisin A as a preservative in various emulsified and non-emulsified sauces and dips (e.g., mayonnaise, ketchup, cheese sauce), as well as in heat-treated processed meat products.
- ❖ The revisions clarify the application of Notes 538 and 330, allowing flexibility for different oil content levels in sauces and ensuring that exclusions (e.g., canned products) are clearly communicated. Technologically, nisin serves as a bacteriocin to prevent microbial growth and ensure food safety, particularly in low- to medium-oil formulations.
- ❖ JECFA's 2024 evaluation reaffirmed the ADI of 0–2 mg/kg bw for nisin A, confirming no significant risk for antimicrobial resistance or microbiome disruption. Technological need is supported by the limitations of nisin in high-fat products, which can be mitigated using synergistic preservative strategies or encapsulation technologies. The proposal aligns with international practice, as some countries (e.g., Australia, Japan) allow nisin without special notes, and the proposed clarification improves regulatory consistency without introducing additional consumer risk.

6) Dimethyl Dicarbonate (DMDC, INS 242) – Submitted by International Food Additives Council (IFAC)

- ❖ The proposal introduces a new provision for DMDC as a preservative in aromatized alcoholic beverages (e.g., beer, wine, low-alcohol refreshers) at a maximum use level of 250 mg/kg. DMDC acts as a microbial control agent during beverage filling by inactivating key microbial enzymes, thereby prolonging shelf life without affecting flavor or color.
- ❖ Technologically, it functions as a cold sterilization agent, protecting beverages during processing and ensuring product stability.
- ❖ JECFA's 1990 evaluation found the additive acceptable when used according to good manufacturing practices, and no ADI was specified. Dietary intake assessments indicate minimal residual DMDC, as it hydrolyzes into methanol and carbon dioxide before consumption. The use does not mislead consumers, as the additive is largely absent from the finished product, and its function is transparent.

7) Steviol Glycosides (INS 960) – Submitted by International Stevia Council (ISC)

- ❖ The proposal seeks to revise provisions for steviol glycosides in beverage whiteners and cream analogues, and to delete Note XS243 in flavored fluid milk drinks (FC 01.1.4) and dairy-based desserts (FC 01.7), aligning the GSFA with the Standard for Fermented Milks (CXS 243-2003). Technologically, steviol glycosides serve as high-intensity sweeteners, enabling reduced-sugar or sugar-free formulations without adding calories, meeting consumer demand for healthier products.

- JECFA's 2023 evaluation established an ADI of 0–4 mg/kg bw, confirming safety for the proposed food categories. The deletion of Note XS243 restores coherence between the GSFA and the corresponding commodity standard, while the maximum use levels do not result in ADI exceedance. Use is not misleading, as the sweetener's function is clearly declared, and it continues to provide the same technological effect as other permitted sweeteners.

8) Ascorbyl Palmitate and Ascorbyl Esters (INS 304/305) – Submitted by International Special Dietary Foods Industries (ISDI)

- The proposal revises existing provisions for ascorbyl palmitate and ascorbyl stearate as antioxidants across multiple infant formulae, follow-up formulas, formulae for special medical purposes, beverage whiteners, milk powders, cheeses, dairy desserts, fat spreads, and other food categories.
- Technologically, these additives prevent oxidation of fats and sensitive nutrients, preserving product quality, nutrient content, and organoleptic properties throughout processing, storage, and consumer use. Modern formulations with higher levels of unsaturated fatty acids increase oxidative risk, making enhanced antioxidant protection necessary.
- JECFA's 2025 evaluation (100th Meeting) established a group ADI "not specified," indicating that the additives do not represent a health hazard at the proposed concentrations. Refined dietary intake assessments confirm safety, including for infants under 12 weeks of age. The proposed revisions harmonize use levels, maintain safety, and are not misleading, as the additives' antioxidant function is declared on product labels.

Overall Assessment

- Across all proposals, there is a clear reliance on robust scientific evaluations conducted by JECFA, along with well-defined technological justifications that are consistent with the principles of the GSFA. The proposals also reflect an increasing trend toward broader application of additives across multiple food categories, driven by technological innovation and market demands.
- At the same time, the expansion of uses highlights the need for careful consideration of cumulative dietary exposure, particularly when additives are permitted in a wide range of foods. Ensuring harmonization of maximum use levels and conditions across food categories remains essential to support consistency and facilitate international trade. In addition, maintaining transparency through clear labelling provisions is critical to uphold consumer confidence and protection.

Comments and Discussion

- While the technological justifications are generally well supported, some proposals raise issues that merit careful consideration. For example, extensions of use to additional food categories (e.g. Gardenia Blue) rely on the assumption of minimal incremental exposure; however, cumulative exposure across multiple categories should continue to be monitored. Similarly, proposals involving broad category coverage (e.g. rosemary extract across numerous food groups) require attention to combined dietary exposure and consistency with commodity standards where antioxidants may not be permitted.

- Clarification of notes (e.g. for nisin and annatto extracts) is beneficial for regulatory clarity, but care should be taken to ensure that revised wording does not unintentionally broaden uses beyond what was originally assessed for safety.

- For steviol glycosides, the removal of restrictions or notes appears justified from a technological and exposure perspective, but alignment with commodity standards (e.g. fermented milk standards) will be important to avoid inconsistencies.

- For additives used in infant foods, proposals are supported by recent JECFA evaluations; however, given the vulnerability of the target population, a cautious approach is warranted, ensuring strict adherence to specified maximum levels and continued post-market monitoring.

Conclusion and Recommendations

- Overall, the proposals are scientifically substantiated and consistent with the criteria of the GSFA Preamble, particularly regarding technological need, safety, and non-misleading use. Most additives have been recently evaluated by JECFA, with exposure estimates indicating no appreciable health risk under proposed conditions of use.

In this context, it is recommended to:

1. Support the adoption of proposals that are clearly aligned with JECFA evaluations and demonstrate low exposure relative to ADIs.
2. Endorse revisions aimed at clarifying notes and improving consistency, provided they do not expand uses beyond assessed safety limits.
3. Ensure alignment with existing Codex commodity standards, especially where discrepancies or exclusions exist.
4. Apply a cautious approach for additives intended for infant foods, maintaining strict compliance with evaluated safe levels.
5. Emphasize the importance of comprehensive dietary exposure assessments, particularly for additives with expanded or multiple uses across food categories.
6. Ensure strict adherence to GSFA principles, including clear technological justification and the requirement that use does not mislead consumers.
7. Promote greater harmonization of maximum use levels and provisions across food categories to reduce inconsistencies and trade barriers.
8. Highlight the importance of clear and transparent labelling to support informed consumer choice.
9. Where uncertainties remain, support a stepwise approach to adoption, allowing for the generation of additional data and further evaluation if needed.

G. Agenda Item 8: Standard for baker's yeast

Document Number: CX/FA 26/56/11; CX/FA 26/56/11 Add.1

Status in Codex Process: Step 4

Background

- At the 44th Session of the Codex Alimentarius Commission (CAC44, 2021), China introduced a proposal for new work on the development of a Codex standard for yeast, highlighting its widespread global use and the absence of a dedicated Codex committee with a clear mandate to address this product. CAC44 agreed that further consideration was needed and requested that a discussion paper be submitted to the (CCFA).
- At CCFA53 (2023), China presented the discussion paper (CRD6), emphasizing that baker's yeast is a food ingredient (classified under the Food Category System, FC 12.8) rather than a food additive, and underscored the need for a Codex standard to protect consumer health and facilitate fair international trade in line with the Codex Strategic Plan 2020–2025. CCFA agreed that further work was warranted and requested China, France, and interested Members to prepare a revised discussion paper for consideration at CCFA54.
- At CCFA54 (2024), the revised project document prepared by the Electronic Working Group (EWG) was discussed. While some Members questioned the necessity of the standard due to the absence of identified trade issues, and concerns were raised regarding potential overlap with existing ISO standards, China clarified that Codex standards serve distinct purposes, particularly in supporting WTO agreements. CCFA54 agreed to forward the proposal to CAC47 for approval as new work and established an EWG, chaired by China and co-chaired by France and Türkiye, to develop the draft standard.
- At CAC47 (2024), the Commission approved the new work proposal for the development of a Codex standard for baker's yeast.
- At CCFA55 (2025), the Committee considered the proposed draft standard for baker's yeast at Step 4, as prepared by the EWG. The Committee acknowledged the progress made and agreed that further refinement was necessary, particularly with regard to the scope, definition, and alignment with existing Codex texts, including the General Standard for Food Additives (GSFA). The draft standard was therefore returned for further revision, taking into account the comments received.
- In 2025, an Electronic Working Group (EWG) was established with the participation of 25 members and 1 observer to develop the standard on baker's yeast. Two rounds of consultation were organized, allowing for the collection of comments from several countries and an observer (the European Confederation of Yeast Producers -COFALEC).
- At CCFA56 (2026), the revised draft standard for baker's yeast will be presented again at Step 4 for further consideration, with a view to addressing outstanding issues and progressing the draft through the Codex step procedure.

Analysis

- The Electronic Working Group (EWG) reviewed the draft standard for baker's yeast and expressed overall support for its provisions.
- The EWG reviewed an initial draft based on the outcomes of the 55th session of CCFA. The EWG also reviewed and improved earlier drafts by addressing two main areas: (i) clarification of the

scope and technical provisions of the standard, and (ii) consideration of broader issues such as genetically modified (GM) yeast.

- Several aspects remain under discussion: Justification and scope of food additives, structure and presentation of additive provisions. These issues are mainly technical and do not affect the core structure of the standard but require resolution for final adoption.

Key EWG Revisions

1) Sections 1 and 2: Scope and Description

Important clarifications were introduced, particularly regarding the fact that baker's yeast is not intended for direct consumption, as well as its definition and classification. Structural improvements were made, while the process description was considered adequate. The definition of semi-dry yeast was further refined for greater precision.

2) Section 3: Quality Factors

Adjustments were made to moisture content and the presentation of yeast types, improving the consistency of the table. Clarifications were also provided regarding ingredients and pH, limiting certain requirements to specific yeast types and reducing ambiguity.

3) Section 4: Food Additives

Discussions remain ongoing on key aspects, including the technological justification for additives and their presentation (notably alignment with the GSFA). Processing aids were also considered. The second round of comments contributed to a more harmonized and descriptive approach, aligned with other Codex standards and better reflecting industry practices.

4) Section 7: Labelling

A proposal was adopted to require "baker's yeast" as the mandatory product name, while allowing the term "yeast" as an optional designation, provided it is not misleading. This ensures regulatory clarity and improves consumer information.

5) Other Issue: Genetically Modified (GM) Yeasts

Proposals to explicitly include provisions on genetically modified yeasts were not retained. It was agreed to follow existing Codex guidance and procedures, ensuring consistency and avoiding potential trade barriers.

Proposed Draft Standard

The proposed revisions are presented in the Appendix II (CX/FA 26/56/11 Appendix II).

1) Scope and product definition

The draft standard clearly defines baker's yeast as *Saccharomyces cerevisiae*, used as a biological leavening agent in bakery products . The clarification that baker's yeast is **not a ready-to-eat product** is important for regulatory and safety considerations.

The scope is appropriate and aligned with Codex principles, ensuring clarity and preventing misclassification.

2) Product Classification

The standard classifies baker's yeast into: Fresh yeast (block, granulated, liquid) and Dry yeast (active dry, instant, semi-dry). The classification is based on: Moisture content and Physical form. This classification is practical and reflects industry practices. It facilitates quality control, trade standardization and consumer understanding.

3) Quality and Composition Requirements

The draft specifies moisture ranges for all types and pH requirements only for liquid (cream) yeast. Moisture is a critical parameter affecting shelf life and functionality. Limiting pH requirements to liquid yeast is scientifically justified and avoids unnecessary constraints on other forms.

4) Food Additives and Processing Aids

The draft allows the use of Antioxidants, emulsifiers, preservatives, stabilizers, etc. In accordance with the General Standard for Food Additives (GSFA). Additives are not listed individually but by functional classes. This approach ensures flexibility and consistency with GSFA. However, it may reduce transparency compared to listing specific additives so further clarification on technological justification may be needed.

5) Treatment of Genetically Modified Yeast

The draft does not include specific provisions for genetically modified (GM) yeast. This is consistent with Codex practice, and It avoids unnecessary trade complications

6) Labelling Provisions

The product must be labelled as: "Baker's yeast" or corresponding product name -The term "yeast" is allowed if not misleading.

Key discussions and Comments

❖ Two rounds of Electronic Working Group (EWG) consultations were conducted to gather feedback on the draft standard for baker's yeast. **Table 1** summarizes the key discussion points and outcomes from Rounds 1 and 2, highlighting how the draft standard was revised and clarified based on members and Observers input.

Table 1: Key Discussion Points and Outcomes from EWG Consultations

Round	Key Discussion Points	Outcomes / Actions Taken
Round 1	– Scope & Definition: Baker's yeast (*Saccharomyces cerevisiae*), biological leavening agent, not ready-to-eat. – Classification: Fresh (block, granulated, liquid) and Dry (active dry, instant, semi-dry); based on moisture & physical form – Justification for food additives (types, levels, technological need) – Use of moisture content as the sole classification criterion – Consideration of "compressed yeast" and separate category for semi-dry yeast	– Scope clarified; yeast confirmed as not ready-to-eat ; Colour updated to ivory – Functional class approach adopted for additives; aligned with GSFA – GM yeast excluded, consistent with Codex practice – Moisture and pH requirements scientifically justified and retained only where needed

	– Potential inclusion of GM yeast	– Tables adjusted for clarity and consistency
Round 2	– Clarification of "other ingredients" vs. food additives – More precise definition of semi-dry yeast (particle form, size, storage, usage) – Processing aids inclusion and presentation format. – Removal of reverse carry-over principle reference. – Refinement of food additive presentation and alignment with GSFA – Moisture and pH requirements by yeast type (pH specifications for liquid/cream yeast only) – Labelling: mandatory "baker's yeast", optional "yeast" allowed to avoid conflicts with future yeast standards	– "Other ingredients" confirmed to refer to non-additive components (e.g., oils, enzymes) – Reverse carry-over reference deleted (covered by GSFA, CXS 192-1995) – pH requirements are retained only for liquid/cream yeast – Semi-dry yeast definition refined for clarity and alignment with other types – Processing aids aligned with Codex commodity standard practices – Labelling provision adopted: "baker's yeast" mandatory; "yeast" optional if not misleading

- The document CX/FA 26/56/11 Add.1 compiles comments received from Canada, Egypt, the European Union, Peru, Türkiye, Uganda, the Confederation of European Yeast Producers (COFALEC), Food Industry Asia (FIA), and the International Commission for Uniform Methods of Sugar Analysis (ICUMSA) in response to CL 2026/21-FA1, issued in January 2026. These submissions provide technical, regulatory, and practical feedback on the Draft Standard for Baker's Yeast and serve as a basis for the Electronic Working Group (EWG) to refine the draft standard.

Table 2: Detailed Members and Observers' Sectional Comments (CX/FA 26/56/11 Add.1)

Section	Key Comments / Discussions	Submitted by / Remarks
General	Recognition of the EWG's work; proposals to reference ISO 23983:2025 for alignment; general appreciation for clarity improvements.	Egypt, Peru, COFALEC
Scope	Suggested including sampling and test methods; clarified that baker's yeast is a food ingredient for direct sale and food manufacture; minor editorial improvements for clarity.	Canada, Uganda
Product Definition	Questioned "produced by multiplication of pure strains" due to presence of wild yeast; requested inclusion of double yeast characteristics.	ICUMSA, Uganda
Types (Fresh Yeast)	Proposals to refine descriptions of block/compressed, granulated, and liquid yeast; incorporate definitions into section	Canada, Peru, Egypt

	2.2 for clarity; ensure odour and absence of extraneous materials; flexibility for local practices.	
Types (Dry Yeast)	Suggest modification of color description from "ivory-coloured" to "ivory to light brown" to reflect natural variability; classify into active, instant, semi-dry types; define particle size and usage method; minor editorial improvements.	Canada, Türkiye
Essential Composition & Quality Factors	Include general requirements: color, odour, absence of extraneous materials, no signs of deterioration; align moisture requirements with ISO 23983:2025; clarify pH only for liquid yeast; include physicochemical parameters (starch, dispersibility, fermenting power, dough-raising capacity).	Uganda, Canada, FIA, COFALEC
Food Additives	Functional classes (antioxidants, emulsifiers, etc.) acceptable; avoid listing preservatives unless justified; processing aids should comply with CXG 75-2010 or be detailed; textual description preferred for alignment with other Codex standards.	EU, Canada
Food Hygiene	Products should comply with CXC 1-1969, other relevant Codex hygiene codes, and microbiological criteria (CXG 21-1997); propose limits for coliforms, E. coli, Salmonella, Staphylococcus aureus, and rope spores.	Canada, Uganda
Labelling	Product name to be "Baker's yeast" with specification of type (dry/fresh); optional use of "yeast" permitted if not misleading; reference to CXS 107 for food additives labelling; ensure consumer clarity.	Uganda
Packaging, Transportation, Storage	Fresh yeast must be stored at 1–7°C; packaging must protect product quality and be odorless; aligns with EU and Peru proposals.	Peru, EU
Outstanding Issues	Further discussion needed on justification, scope, and presentation of food additives; no inclusion of GM yeast to avoid trade barriers.	EWG consensus

Regional Considerations

- Regionally, the development of this standard is highly relevant, particularly for countries with strong bakery sectors, including traditional bread production and the import/export of yeast products.
- The development of this standard has direct implications for trade, food security, and small and medium-sized enterprises (SMEs). and the establishment of harmonized specifications is expected to:
  - Harmonizes technical specifications for yeast.
  - Supports regional and international trade.
  - Enhances food safety and product consistency;
  - Provides a reference framework for national regulations.

Conclusion and recommendations

- The draft standard for baker's yeast provides a clear and coherent framework aligned with Codex principles and industry practices. While minor technical issues remain, particularly regarding food additives, the draft is sufficiently advanced to progress within the Codex procedure and to support harmonization, international trade, and consumer protection.

- In light of the discussions and proposed revisions, it is recommended to:
  - Support the progression of the draft standard to the next step in the Codex procedure, subject to address outstanding issues.
  - Encourage further clarification on technological justification for food additives
  - Support the current scope and classification, as they are consistent with industry practices and Codex principles.
  - Maintain alignment with GSFA while considering improved transparency in additive provisions.
  - Support the exclusion of GMO-specific provisions, in line with existing Codex practice

H. Agenda Item 10: Discussion paper on the development of a guideline for the conduct of food safety assessment of cell culture media components used in the production of cell-based foods

Document Number: CX/FA 26/56/13

Status in Codex Process: N/A

Background

- In 2022, the FAO and WHO conducted a comprehensive food safety hazard identification of cell-based food production. While some hazards are already known and exist in conventionally produced foods, there are additional hazards unique to the production of cell-based foods due to the nature of the material inputs and equipment used that may not have been used previously for food production. For instance, the use of novel culture media components (e.g. certain growth factors, small molecules) during the production process introduces a need to appropriately assess their potential food safety risks.

- At CAC44 (2021) Cell-based food were first discussed at Codex as part of discussions on New Food Sources and Production Systems (NFPS) in response to a FAO-WHO document seeking advice on addressing NFPS related issues. Subsequently, a Circular Letter (CL 2023/31/OCS-CAC) was issued on the topic and further discussion held at CAC45 (2022).

- During CCFA53 (2023) and CCFA54 (2024), the Committee began exploring the safety and regulatory aspects of substances used in cell culture media. Members noted that these components are used in production rather than as final ingredients and that current food additive standards do not fully address their potential risks. The need for harmonized guidance to ensure consumer safety and facilitate fair trade was recognized.

- At CAC46 (2023), Members and Observers recognized the importance of New Food Sources and Production Systems (NFPS) and the role Codex could play in addressing related challenges. The meeting confirmed that existing Codex mechanisms are adequate for new work proposals on NFPS and encouraged the submission of discussion papers or proposals to Codex Committees or the Executive Committee.

- At CCEXEC86(2024), Singapore proposed two new work initiatives on cell-based foods: a guideline for safety assessment of cell culture media components and a code of hygienic practice for their manufacture. The Executive Committee recommended submitting the safety guideline to CCFA and the hygienic code to CCFH.

- At CAC47(2024), the proposals by Singapore and China were highlighted, and member countries expressed general interest. Singapore and Saudi Arabia also co-hosted a side event to raise awareness of cell-based foods and Codex's role in addressing their safety.

- At CCFA55, Singapore and China formally submitted the proposal on developing guidelines for assessing cell culture media components. Members supported the need for Codex guidance to ensure consumer safety and fair trade practices. An Electronic Working Group (EWG) was established, chaired by Singapore and co-chaired by China, Republic of Korea, and Saudi Arabia, with terms of reference to:
  - Revise the draft project document for CCFA56.
  - Develop a categorization framework with evidence requirements for safety assessment.
  - Identify areas requiring FAO/WHO scientific advice to support risk assessment frameworks.
- At CCFA56 (2026), the revised project document will be presented for consideration.

Analysis

- The EWG recognized the diversity of media components and the lack of existing internationally harmonized guidelines, making this work essential for future regulatory consistency and addresses the need for internationally harmonized guidance on the safety assessment of cell culture media components used in cell-based foods.
- The development of the current Discussion Paper involved significant international consultation, with participation from 32 member countries, 1 member organization, and 6 observer organizations.
- The EWG also developed a preliminary draft guideline and a categorisation framework for cell culture media components. This framework introduces a tiered approach, whereby the level of evidence required for safety assessment is proportional to the level of potential risk and novelty of the component.
- Cell-based foods rely on animal cells cultured in complex cell culture media containing salts, sugars, amino acids, vitamins, growth factors, hormones, small molecules, and, in some cases, antimicrobials. While some components are familiar in conventional foods, others are novel inputs that may remain in the final product, posing potential food safety risks.
- The EWG highlighted that safety assessment is critical to prevent health risks while supporting the growth of this emerging food sector.
- The scope was refined to focus on components for animal cell-based foods (meat and seafood), excluding plant-based cells and scaffolds at this stage. A forward-looking footnote acknowledges potential future expansion as technology evolves.

Synthesis of EWG Appendices on Cell Culture Media Safety Assessment

- The appendices developed by the Electronic Working Group (EWG) provide a structured basis for establishing internationally harmonized guidelines for the safety assessment of cell culture media components used in cell-based foods. Each appendix contributes distinct but complementary information, ranging from the justification for the work to technical guidance and scientific questions. Together, they form a coherent framework to guide CCFA members in assessing safety, supporting trade, and accommodating future developments in the industry.

- **Appendix 1: Discussion Paper**

  This document presents the rationale for the new work, highlighting the emergence of cell-based foods, the novelty of certain media components, and gaps in current Codex guidance. It frames the need for harmonized safety assessment, defines the initial scope (animal cell-based foods), and provides background on relevant Codex discussions.

- **Appendix 2: Project Document**

  The project document formalizes the objectives and terms of reference of the proposed work. It defines the guideline's purpose, establishes the tiered categorization framework for assessing component risk, and identifies areas requiring FAO/WHO scientific input. It serves as the official basis for CCFA56 consideration.

- **Appendix 3: Draft Guideline and Categorization Framework**

  This draft outlines a tiered approach for categorizing media components based on risk and novelty. It provides technical guidance on safety evaluation, introduces a glossary of terms, and incorporates scientific tools such as the Threshold of Toxicological Concern (TTC). The draft is preliminary and intended as a foundation for further discussion.

- **Appendix 4 – List of Questions for FAO/WHO Scientific Advice**

  This appendix consolidates technical questions to be submitted to FAO and WHO, covering toxicology, potential residues, exposure assessment, and data requirements.

Key Discussion points and Comments

- Discussions within the EWG focused primarily on the scope, scientific complexity, and policy implications of the proposed work as summarized in the table below.

- The EWG conducted two rounds of consultation, during which all member suggestions and comments were carefully reviewed and incorporated where appropriate.

Table 1: Key Discussion Points and Outcomes

Section / Topic	Key Discussion Points	Outcomes / Actions Taken
Scope	Expansion beyond animal cells (e.g., cultured milk, cocoa)	Maintained scope limited to animal cell-based foods. Footnote added for future applicability.

	Inclusion of scaffolds for structured products	Excluded scaffolds at this stage; future consideration allowed as technology evolves.
Antimicrobial Use & Resistance (AMR)	Potential contribution of antimicrobials to AMR	Clarified antimicrobials are used only in early cell line development, not final production. References to AMR considerations and relevant Codex texts added.
Trade Considerations	Low current trade volume of cell-based foods	Codex approach: proactive on emerging technologies, independent of trade volume. Trade volume noted but not limiting.
Sustainability and Neutral Approach	Environmental impact of cell-based food production	References to sustainability removed due to insufficient evidence; adopted a neutral, science-based approach.
Categorisation & Risk Assessment Framework	Tiered evidence requirements; Threshold of Toxicological Concern (TTC)	Developed a preliminary categorisation framework for tiered, risk-based assessment. Further technical validation required.
Alignment with Codex Risk Analysis Principles	Ensuring robustness, transparency, proportionality	Framework aligned with Codex principles, emphasizing evidence-based assessment without presupposing outcomes.
Technical and Procedural Readiness	Areas needing scientific input: novel substances, exposure assessment, risk assessment methods, data requirements	Consolidated list of questions for FAO/WHO consultation to support guideline development.
Technical Scope Clarification	Focus on media components rather than final products	Scope clearly defined to maintain technical focus, avoiding overlap with other regulatory assessments.

Conclusion and recommendations

- The draft project document and supporting materials developed by the EWG provide a solid foundation for establishing internationally harmonized guidelines on the safety assessment of cell culture media components used in cell-based foods.
- The work clearly defines the initial scope (animal cell-based foods), introduces a risk-based, tiered framework for evaluating media components, and identifies areas requiring FAO/WHO scientific input.
- While technical details remain preliminary, the documents collectively offer a structured approach to support consumer safety, facilitate trade, and guide future developments as the cell-based food industry evolves.
- The guideline is designed to be adaptable, allowing for future inclusion of non-animal cells and scaffolds once industry practices mature. By proactively addressing potential safety risks of media components, this initiative aligns with Codex's mandate to protect public health while supporting innovation and harmonized international standards.
- In light of the discussions and proposed revisions on the development of a guideline for the conduct of food safety assessment of cell culture media components used in the production of cell-based foods, it is recommended to:
    - Approve the new work proposal for the development of a guideline for the conduct of food safety assessment of cell culture media components used in cell-based foods.
    - Limit the initial scope to animal cell-based foods, while allowing for potential future expansion to non-animal cells and scaffolds.

- Adopt the tiered, risk-based categorization framework for safety assessment of media components, ensuring evidence requirements correspond to potential risk and novelty.
- Request FAO/WHO scientific advice on toxicology, potential residues, exposure assessment, and other data requirements to ensure scientific robustness.
- Ensure alignment of the guideline with Codex risk analysis principles, supporting consistent and internationally harmonized assessments.
- Consider the draft guideline and categorization framework as preliminary, forming the basis for further technical discussions and refinement once the new work is approved.